

United States within the global economy; expand economic opportunities in rural America and enhance the quality of life for farmers, rural citizens, and society as a whole; improve the productivity of the American Agricultural system and develop new agricultural crops and new uses for agricultural commodities; develop information and systems to enhance the environment and the natural resource base upon which a sustainable agricultural economy depends; or enhance human health. Therefore, in carrying out its review under §3411.14, the peer review group shall take into account the following factors unless, pursuant to §3411.5(a), different evaluation criteria are specified in the program solicitation:

- (a) Scientific merit of the proposal.
- (1) Conceptual adequacy of hypothesis;
- (2) Clarity and delineation of objectives;
- (3) Adequacy of the description of the undertaking and suitability and feasibility of methodology;
- (4) Demonstration of feasibility through preliminary data;
- (5) Probability of success of project; and
- (6) Novelty, uniqueness and originality.

(b) Qualifications of proposed project personnel and adequacy of facilities.

(1) Training and demonstrated awareness of previous and alternative approaches to the problem identified in the proposal, and performance record and/or potential for future accomplishments;

(2) Time allocated for systematic attainment of objectives;

(3) Institutional experience and competence in subject area; and

(4) Adequacy of available or obtainable support personnel, facilities, and instrumentation.

(c) Relevance of project to long-range improvements in and sustainability of United States agriculture or to one or more of the research purposes outlined in the first paragraph of this section.

(1) Scientific contribution of research in leading to important discoveries or significant breakthroughs in announced program areas; and

(2) Relevance of the research to agricultural, environmental, or social needs.

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PART 3415—BIOTECHNOLOGY RISK ASSESSMENT RESEARCH GRANTS PROGRAM

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Subpart A—General

§ 3415.1 Applicability of regulations.

(a) The regulations of this part apply to research grants awarded under the authority of section 1668 of the Food, Agriculture, Conservation, and Trade Act of 1990, (7 U.S.C. 5921). Grants awarded under this section will support biotechnology risk assessment research to help address concerns about the effects of introducing certain biotechnology products into the environment and to help regulators develop policies concerning the introduction of such products. Taking into consideration any determinations made through consultations with such entities as the Animal and Plant Health Inspection Service, the Forest Service, the Environmental Protection Agency,

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the Office of Agricultural Biotechnology, and the Agricultural Biotechnology Research Advisory Committee, the Administrators of CSREES and ARS shall determine and announce, through publication of a Notice in such publications as the FEDERAL REGISTER, professional trade journals, agency or program handbooks, the Catalog of Federal Domestic Assistance, or any other appropriate means, specific areas of research for which preproposals or proposals will be solicited and the extent that funds are available therefor.

(b) The regulations of this part do not apply to grants awarded by the Department of Agriculture under any other authority.

§ 3415.2 Definitions.

As used in this part:

(a) *Ad hoc reviewers* means experts or consultants qualified by training and experience in particular scientific or technical fields to render special expert advice, through written evaluations of grant applications, in accordance with the provisions of this part, on the scientific or technical merit of grant applications in those fields.

(b) *Administrator* means the Administrator of the Cooperative State Research, Education, and Extension Service (CSREES) and/or the Administrator of the Agricultural Research Service (ARS) and any other officer or employee of the Department of Agriculture to whom the authority involved may be delegated.

(c) *Awarding official* means the Administrator and any other officer or employee of the Department to whom the authority to issue or modify grant instruments has been delegated.

(d) *Biotechnology* means any technique that uses living organisms (or parts of organisms) to make or modify products, to improve plants or animals, or to develop microorganisms for specific use. The development of materials that mimic molecular structures or functions of living systems is included.

(e) *Budget period* means the interval of time (usually 12 months) into which the project period is divided for budgetary and reporting purposes.

(f) *Department* means the Department of Agriculture.

(g) *Grant* means the award by the Administrator of funds to a grantee to assist in meeting the costs of conducting, for the benefit of the public, an identified project which is intended and designed to establish, discover, elucidate, or confirm information or the underlying mechanisms relating to a research program area identified in program solicitation.

(h) *Grantee* means the entity designated in the grant award document as the responsible legal entity to whom a grant is awarded under this part.

(i) *Peer review group* means an assembled group of experts or consultants qualified by training and experience in particular scientific or technical fields to give expert advice, in accordance with the provisions of this part, on the scientific and technical merit of grant applications in those fields.

(j) *Principal investigator* means a single individual who is responsible for the scientific and technical direction of the project, as designated by the grantee in the grant application and approved by the Administrator.

(k) *Project* means the particular activity within the scope of one or more of the research program areas identified in the annual program solicitation that is supported by a grant under this part.

(l) *Project period* means the total time approved by the Administrator for conducting the proposed project as outlined in an approved grant application.

(m) *Research* means any systematic study directed toward new or fuller knowledge and understanding of the subject studied.

(n) *Methodology* means the project approach to be followed to carry out the project.

§ 3415.3 Eligibility requirements.

(a) Except where otherwise prohibited by law, any public or private research or educational institution or organization shall be eligible to apply for and to receive a grant award under this part, provided that the applicant qualifies as a responsible grantee under the criteria set forth in paragraph (b) of this section.